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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,965	01/12/2001	Matthew Thomas Heisey	106281 / 0528224	1681

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EXAMINER
CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
10/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/759,965	HEISEY ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 20, 2007 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,9,11,12 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9,11,12 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **3, 5-6, 10, 13-42 and 44-50** were previously cancelled, claims **7-8** have also been cancelled, claims **1, 9 and 43** have been amended, and no new claims have been added as per the amendment filed August 20, 2007. A Terminal Disclaimer filed October 8, 2002 has been found acceptable and entered. No additional Information Disclosure Statements (IDSs) have been received as of the mailing date of this Office action.

Claims **1-2, 4, 9, 11-12 and 43** remain in the case.

Rejections previously made under 35 U.S.C. § 112, first paragraph, have been found to be moot in view of applicant's amendments. These rejections have therefore not been maintained.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-2, 4, 9, 11-12 and 43** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Nutramax Laboratories '816** (PTO-1449 ref. **CA**) in view of **Florio '715** (PTO-1449 ref. **BF**), **Martino '692** (PTO-1449 ref. **BM**), **Burger '919** (PTO-14549 ref. **BG**), **Murad '594** (PTO-1449 ref. **BE**), and **Herschler '878** (PTO-1449 ref. **AU**) and further in view of **applicant's own admissions, Vanderveen et al.** (PTO-892 ref. **U**) and **Swinyard et al.** (PTO-892 ref. **V**).

The instant claims are directed to beverage (liquid) compositions containing cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine and numerous additional nutritional and non-nutritional additional ingredients and carriers for the purpose of treating arthritis, and a kit for this specific purpose including written instructions for the administration/consumption of the composition to, or by, an end user in need thereof.

Nutramax Laboratories '816 (PTO-1449 ref. **CA**) discloses the administration of compositions including glucosamine, chondroitin, and optionally various vitamins and minerals (nutrients) for the treatment of arthritis in mammals.

Florio '715 (PTO-1449 ref. **BF**)discloses the administration of compositions including glucosamine, chondroitin, and optionally lipids/fatty acids in liquid form including administration instructions for the treatment of arthritis in mammals.

Marino '692 (PTO-1449 ref. **BM**) discloses the administration of compositions including cartilage, glucosamine, chondroitin, and optionally various nutrients for the treatment of arthritis in mammals.

Burger '919 (PTO-1449 ref. **BG**; also specifically cited by applicant's disclosure) discloses the administration of compositions including glucosamine, and optionally lipids/fatty acids for the treatment of arthritis in mammals.

Murad '594 (PTO-1449 ref. **BE**) discloses the administration of compositions including glucosamine, chondroitin, and optionally nutrients including vitamins and minerals for the treatment of arthritis in mammals.

Herschler '878 (PTO-1449 ref. **AU**) discloses the administration of compositions including methylsulfonylmethane, and optionally as part of a nutrient (food) for the treatment of arthritis in mammals.

Applicant's own admissions: at page 1, original lines 12-13, applicant admits that the prior art teaches the effectiveness of glucosamine and chondroitin in the treatment of osteoarthritis (hereinafter "arthritis"). Applicant also admits in the same paragraph that numerous commercial products in this art area are readily formulated into beverage compositions immediately prior to consumption. At the top of page 2, applicant further admits that "[c]hondoprotective agents may be delivered in the form of compositions having high sugar content." Applicant also admits at page 11, last full paragraph, that methylsulfonylmethane is known in the prior art to have been administered to treat arthritis. Applicant admits at page 12, three lines from the bottom of the page, that "[s]weetening agents are commonly known in the art," and at lines 9-11 of page 12 also admits that certain naturally occurring sweeteners are well known in that art. At the top of page 14, applicant also admits that other commercially available sweeteners including "saccharin" are well known in the art.

Vanderveen et al. (PTO-892 ref. **U**) in chapter 51 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Vitamins and Other Nutrients," discloses a long list of

substances normally found in food stuffs including the nutrients "glucose," "fats and oils," and "fructose."

Swinyard et al. (PTO-892 ref. **V**)in chapter 66 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Pharmaceutical Necessities," discloses numerous substances included within the instant claims including generically "flavoring agents" including "saccharin," "cherry juice," "raspberry juice," and "sucrose," "Vehicles" and "Diluting Agents" including water, "Emulsifying and Suspending Agents," "Pharmaceutical Solvents" including "water," and "Miscellaneous Pharmaceutical Necessities" including "lactose."

Applicant's disclosure does not provide any showing of unexpected results. Therefore, applicant has merely provided directions for the admixing of active ingredients of known pharmaceutical activity (cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine) each of which has been included in one or more of the cited prior art compositions which are asserted repeatedly in the prior art to be effective in the treatment of arthritis. These pharmaceutical activities are each also admitted by applicant's own disclosure. The additional components of the claimed composition are also well known in the art and are not asserted to be anything other than carriers or pharmaceutical necessities and/or nutrients several of which are specifically listed in the cited art, and none of which are asserted by applicant to represent a critical feature for any final composition. The presence of instructions directed to the end user is also a feature known in the prior art cited above (see ref. **BF**).

In light of applicant's failure to provide any data to support an unexpected benefit from the instant claimed compositions, the instant claimed compositions, kits thereof and methods of administration thereof, are deemed to lack patentable distinction as being nothing more than a mixture of substances known in the prior art as anti-arthritis agents and therefore obvious compositions to be administered to a host in need thereof. Any additional compounds acting in concert has the carrier or excipient (e.g. sweeteners, etc., etc.) have been included in the spirit of making the resultant composition palatable and optionally nutritious as admitted by applicant's own disclosure, and as generically taught by the Vanderveen and Swinyard disclosures.

Therefore, the instant claimed compositions and kits with instructions and methods of administration would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 20, 2007 have been fully considered but they are not persuasive.

Applicant's amendments narrowing the scope of the claimed subject matter are noted with appreciation. However, upon inspection of the instant disclosure, particularly at page 13, lines 21-27, applicant has admitted on the record that erythritol is "well-known," and is a commercially available food additive that is "... commonly used as a bulk sweetener in reduced calorie foods." Therefore, in light of the inclusion above of "applicant's own admissions," the above rejection is deemed to remain valid and has therefore been maintained.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

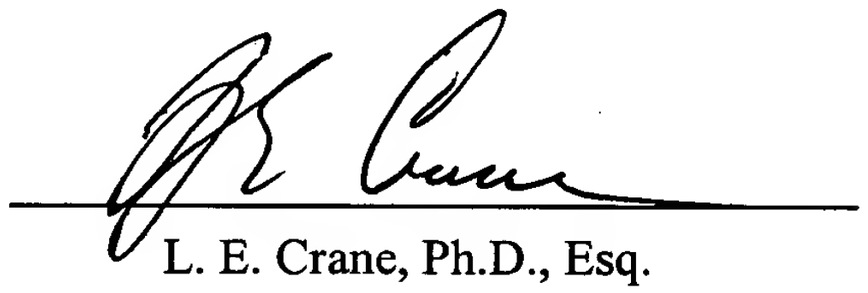
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-**

0651. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
10/23/2007



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